



PHARMACEUTICAL DEVELOPMENT OF BIOPHARMACEUTICALS AND PARTICULARS OF THE CMC DOSSIER



24 – 27 JANUARY 2012

Paul-Ehrlich-Institut, Langen, Germany

- Sources and main characteristics of biopharmaceuticals
- European CMC data requirements for the marketing authorization (Module 3) and for the IMP
- Comparability
- Formulation development
- Isoform characterization and glycosylation of biopharmaceuticals
- Virus and TSE safety
- Stability of biopharmaceuticals
- Bioassay establishment and data presentation
- New approaches in the manufacture - platform technologies and QbD
- CMC Data requirements in the USA and Japan
- The special characteristics of the International Nonproprietary Name system (INN) for biopharmaceuticals

EUCRAF - the European Centre for Regulatory Affairs Freiburg offers in collaboration with the University of Strasbourg the postgraduate Diploma „Regulatory Affairs for Biopharmaceuticals” developed by distinguished experts from authorities, universities and companies. EUCRAF is also a platform for Regulatory Affairs experts to facilitate the exchange on current matters related to biopharmaceuticals.

LIMITED NUMBER OF PLACES ONLY – REGISTER EARLY!

BIOPHARMACEUTICALS ARE SPECIAL – STAY-UP-TO-DATE!

CONTENT

Biopharmaceuticals are special since they stem from a biological source or the protein structure is transcribed from genetic information and is expressed by a living cell. They are usually complex and large and the quality is determined by the manufacturing process where consistency and stability need particular attention. This has implications on the way biopharmaceuticals are developed and regulated and particular guidelines are available which are covered in this seminar. The manufacturing process determines the quality of these products and the requirements for the key quality (CMC) issues are complex accordingly. Issues specific to biopharmaceuticals such as the manufacturing process definition, consistency, stability, definition of specifications, safety of infectious agents, comparability, bioassay are covered in this seminar as well as specific topics such as how changes of the process can have an impact on the quality of these products. In addition to the European requirements on biopharmaceuticals the specific requirements of other global regions are dealt with in detail. Furthermore, the specific requirements for IMPs, investigational medicinal products are covered.

WHO WILL ATTEND:

All those who are working in the regulatory affairs department, in the pharmaceutical, pre-clinical and clinical development of recombinant proteins, monoclonal antibodies, vaccines, ATMPs, blood products, biosimilars. Especially regulatory affairs professionals, CROs involved in development, CEOs and CSOs of start-up SMEs who develop biopharmaceuticals.

FULL PROGRAMME: WWW.EUCRAF.EU

TAKE THIS SEMINAR AS FIRST IN THE SERIES OF NINE TO GET THE POSTGRADUATE DIPLOMA ON REGULATORY AFFAIRS FOR BIOPHARMACEUTICALS

ANNUAL WORKSHOP: WHAT CURRENTLY MATTERS FOR BIOPHARMACEUTICALS IN EUROPE
02 – 03 FEBRUARY 2012

UPCOMING SEMINARS IN 2012

SEMINAR 4.2 (6 – 9 MARCH 2012, Strasbourg)

Non-clinical and clinical development of biopharmaceuticals including biosimilars and the Module 4 and 5 requirements

SEMINAR 5 (19 – 20 APRIL 2012, Freiburg i. Br.)

Specific considerations for the development and authorizations of medicinal products for children

SEMINAR 6 (31 MAY – 1 JUNE 2012, Freiburg i. Br.)

Pharmacovigilance – Post-authorisation surveillance standards to meet regulatory requirements for product safety

SEMINAR 7 (11 – 13 JULY 2012, Strasbourg, EDQM)

The roles of the supervising authorities and the essential characteristics of quality systems

SEMINAR 8 (5 – 7 SEPTEMBER 2012, Freiburg i. Br.)

Scientific advice, regulatory strategy and health technology assessment

SEMINAR 9 (11 – 12 OCTOBER 2012, Freiburg i. Br.)

Good Regulatory Affairs practice: communication skills, project management and tools for the daily practice

SPEAKERS



Michael Ausborn

Global Head Formulation Research,
F. Hoffmann-La Roche



Raffaella Balocco

Manager of the INN-Programm, WHO



Andreas Bechthold

Dean of the Faculty for Chemistry, Pharmacy and
Earth Science, University of Freiburg



Fiona Greer

Global Director, BioPharma Services Development,
SGS M-Scan



Beatrix Metzner

Director – Head of Global Regulatory Oncology EU I,
Merck Serono



Ole Schou

Former Novonordisk



Hans-Joachim Wallny

Technical Project Leader, Novartis



Pascal Wehrle

University of Strasbourg



Hannelore Willkommen

Regulatory Affairs & Biological Safety Consulting



Manuel Zahn

Founder of 3R Pharma Consulting



Course Leaders:
Beatrix Metzner, Merck Serono
Jean-Yves Pabst, University of Strasbourg

24 JANUARY 2012, 10.30 – 18.30

BEATRIX METZNER

- Welcome and Introduction

ANDREAS BECHTHOLD

- Introduction: Sources and main characteristics of biopharmaceuticals
 - Recombinant development of biopharmaceuticals
 - Mammalian, bacterial, yeast, plant expression systems
 - Typical parenteral application
 - Typical characteristics

RAFFAELLA BALOCCO

- International Nonproprietary Name (INN) of biopharmaceuticals

HANNELORE WILLKOMMEN

- Safety of starting material and auxiliary material of animal and/or human origin used in the process or formulation of the medicinal product

25 JANUARY 2012, 9.00 – 18.30

MANUEL ZAHN

- Stability of biopharmaceuticals

MICHAEL AUSBORN

- Formulation and drug product manufacturing of biopharmaceuticals
 - Formulation development
 - Process development
 - Routes of administration
 - PEGylation technologies

HANS-JOACHIM WALLNY

- Bioassay

BEATRIX METZNER

- Quality Module 3 of the CTD for recombinant and classical biopharmaceuticals
 - Overview on Module 3 requirements for biopharmaceuticals
 - Pharmaceutical development
 - MCB/MWCB development
 - Manufacture of drug substance and drug product
 - Consistency in manufacture
 - Process validation: sterility, aseptic process, transport
 - Impurities - sources, detection methods and removal
 - Final product container types
- Characterisation, quality control and analytical techniques
 - Development of analytical methods
 - Characterisation vs routine testing
 - Setting specifications for in-process-controls, finished product release testing and stability testing

26 JANUARY 2012, 9.00 – 17.30

BEATRIX METZNER

- Quality Module 3 of the CTD for recombinant and classical biopharmaceuticals
- Characterisation, quality control and analytical techniques
- Essential differences in Module 3 considerations USA
- Essentials for Module 3 in Japan
- Changes in process and their implications on the molecule, the comparability exercise

27 JANUARY 2012, 8.30 – 16.30

FIONA GREER

- Isoform, molecular subspecies characterisation and glycosylation

OLE SCHOU

- Insulin as an example for use of individual manufacturing methods

PASCAL WEHRLE

- ICH Q8: Introduction into the concept of Quality by Design and Design Space

REGULATORY AFFAIRS FOR BIOPHARMACEUTICALS
SEMINAR 4 PART I: PHARMACEUTICAL DEVELOPMENT OF BIOPHARMACEUTICALS AND PARTICULARS OF THE CMC DOSSIER

Please send your registration form to: **REGISTRATION FORM FOR SEMINAR 4 PART I**
EUCRAF Ltd.,
Wippertstr. 2
79100 Freiburg,
GERMANY

Freiburg, Germany

For any questions, please contact us by phone: +49 (0)761 13 73 44 24
fax: +49 (0)761 13 73 444
email: info@eucraf.eu
or via homepage: www.eucraf.eu

or via email to:
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	Fee	VAT 19%	Total
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<input type="checkbox"/> Academic Institution	1.140,00 €	216,60 €	1.356,60 €

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On receipt of your Registration Form we will confirm your provisional place and provide you with the details of the payment method via e-mail. An invoice will be sent separately. Payment must be received prior to the seminar.

I herewith confirm, that I agree with EUCRAF's Terms and Conditions. For Terms and Conditions, please visit our website at www.eucraf.eu.

Signature

Date

HOW TO REACH

Langen:

Langen is located in the south of Frankfurt (am Main)

By plane:

Frankfurt is served by Frankfurt Airport. From there you can use public transport (40 min) to Langen-Flugsicherung or taxi (20 min) to Langen.

By train:

You can reach Langen-Flugsicherung via Frankfurt am Main (S3/S4) or Darmstadt. <http://www.deutschebahn.com>

By car:

By car you reach Langen via highway A5

VENUE

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YOUR CONTACT PERSON



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HOTEL

There are hotel contingents available in

Hotel Steigenberger
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63225 Langen
Phone: +49 (0)6103 9720
e-mail: frankfurt-langen@steigenberger.de
www.steigenberger.com/Frankfurt-Langen/?source=SH

Achat Hotel
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